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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,601	12/04/2001	Philip Hougaard	452345/0014 JJD/MCD	3498
7590 04/04/2005 STROOCK & STROOCK & LAVAN LLP 180 Maiden Lane New York, NY 10038			EXAMINER SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 04/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/006,601

Applicant(s)

HOUGAARD, PHILIP

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-20, 22-41, 43-60, 62-66, 68-70 and 72-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-20, 22-41, 43-60, 62-66, 68-70 and 72-81 is/are rejected.
- 7) ☒ Claim(s) 63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's amendments and remarks, filed 12/22/04, are acknowledged. Amended claims 1, 20, 23-24, 41, 44-45, 60, 63, 68, and 72 and cancelled claims 8, 21, 42, 61, 67, and 71 are acknowledged.

Applicant's arguments, filed 12/22/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7, 9-20, 22-41, 43-60, 62-66, 68-70, and 72-81 are herein under examination.

#### ***Claim Objections***

Claim 63 is objected to because of the following informality: This claim contains two periods on line 2. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-20, 22-41, 43-60, 62-66, 68-70, and 72-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 2, 3, 10, 11, 12, 15, 16, 24, 27, 31, 32, 33, 36, 37, 45, 49, 51, 52, 53, 56, and 57 recite the phrase “based on” or “based upon” which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met to be considered to be “based on” or “based upon”. Clarification of this issue via clearer claim wording is requested. Claims 4-7, 9, 13-14, 17-19, 22-23, 25-26, 28-30, 34-35, 38-41, 43-44, 46-48, 50, 54-55, 58-60, 62-66, 68-70, and 72-81 are also rejected due to their dependency from rejected claims.

Claims 18, 19, 39, 40, 48, and 59 recite the phrase “the Allen formula” which is vague and indefinite. It is unclear which formula Applicant intends to be used with this phrase as there appear to be many variations of this formula. Page 10 (line 19) of the specification gives one possible Allen formula. But page 13 (lines 6-7) state that other factors needed for Allen’s formula are inserted according to the chosen design. Also, page 14 (lines 14-15) states variation of Allen’s formula are useful in an alternate embodiment. Clarification of which Allen formula to be used in the instant claims 18, 19, 39, 40, 48, and 59 is requested.

Claims 12, 33, and 53 recite the phrase “the Arrhenius formula” which is vague and indefinite as this formula does not appear to be defined in the specification. Clarification of this issue is requested.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10-11, 13-16, 20, 22-29, 31-32, 34-37, 41, 43-47, 49-52, 54-57, 60, 62-66, 68-70, and 72-81 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Levinson et al. (US 2002/0177167).

Levinson et al. disclose a method for planning, performing, and assessing results of pharmaceutical compositions including stability properties (abstract, paragraphs 0016 and 0067). Levinson et al. disclose selecting a plurality of combinations of values of experimental parameters, including amount of dissolved component (release limit variable) (abstract, paragraphs 0070-0074). Levinson et al. disclose a system delivering nanoliter samples for hybridization analysis (paragraphs 0077 and 0080) which represents a selected value for release limit variable for a given specification test. Levinson et al. disclose shelf-life and bioavailability may vary due to chemical interactions, excipients used, and administration use (paragraph 0004). Levinson et al. disclose incubating samples for various lengths of time (shelf-life) such as 5 minutes, 60 minutes, 48 hours, etc. to monitor experiments as a function of time as well as the "ageing process" (paragraph 0086) which represents selecting a desired length of shelf-life, selecting a time at which analysis is performed, and selecting time points for measurements. Levinson et al. disclose selecting various time controlled points because the stability of the first solid-form may not be as stable as other forms over a period of time (paragraph 0086) such that measurements taking of a composition during an middle time point (i.e. 60 minutes as mentioned above) represents selecting a value for the intermediate precision of the measurement, as stated in instant claims 1, 13-14, and 24. This analysis also represents an interim analysis, as stated in

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instant claims 64-65 and 78-81. Levinson et al. disclose selecting distinct combinations of experimental parameters to be measured during the experiment (paragraph 0014) which represents selecting a number of measurements of predetermined test variables. Levinson et al. disclose estimating a property in a chemical composition, generating a predictive model based on experimental result sets according to the property, and the possible formulation changes from an original solid form at different time points of an expected range (paragraph 0016) which represents selecting a value for the expected degradation rate. Levinson et al. disclose preparing samples and then reversing formation of solid-forms (paragraph 0039) which represents degradation. Levinson et al. disclose dissolution rates (paragraph 0036) which represents degradation rates. The Merriam-Webster online dictionary defines dissolution as a dissolving or breakdown of an assembly which represents degradation. Levinson et al. disclose integrating information to maximize the probability of yielding compositions that possess a desired property over an expected range of conditions of manufacture (packaging), storage (shelf-life), and administrations (paragraph 0012) which represents selecting a probability level regarding a level of certainty of the outcome of the study. Levinson et al. disclose collecting data and associating data from previously run experiments (paragraph 0020) which represents basing values on previous long-term studies (note that "long-term" is a broad term that can therefore be any timeframe greater than 0 seconds), as stated in instant claims 2, 13, 15, 16, 27, 34, 36, 37, 49, 54, 56, and 57. Levinson et al. disclose determining optimal formulation and varying parameters (paragraphs 0005, 0009, 0101, 0110) which represents optimizing variables by changing variables, as stated in instant claims 4, 15, 26, 36, and 56. Levinson et al. disclose processing, followed by selecting a set of experimental parameter values and compositions having optimized

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properties (paragraph 0099) which represents optimizing variables by changing one or more variables from multiple experiments, as stated in instant claims 4 and 26. Levinson et al. disclose various properties that may vary with the formulation of a chemical compound, including shelf-life (paragraph 0004), they disclose preparing a crystal form of a compound and calculating expected properties and experimental parameters (paragraph 0025), and repeating calculations (paragraph 0025) which represent calculations and recalculations, as stated in instant claims 3, 5, 28, and 46. The performance of simulations, calculations of expected properties, conducting high throughput experiments, comparing expected and predicted properties, generating a model of experimental parameters and crystals produced, calculating experimental parameters for a second set of crystallization experiments based on the predictive model, and repeating these steps (paragraph 0025) including dissolution rates (degradation rates) (paragraph 0036) represent basing the selected values based on previous accelerated stability studies, as stated in instant claims 11, 14, 32, 35, 52, and 55. Levinson et al. disclose selecting optimal formulations and solid forms whose properties affect stability (paragraph 0004) which represents preparing a batch of a pharmaceutical composition as well as selecting 100% outcome wherein the outcome is broadly and reasonably interpreted to be making of the compound after optimal selection which represents the process of changing one or more variables, as stated in instant claims 1, 4, 6, 7, 25, 29, 47, and 50. Levinson et al. disclose using thousands of experimental formulations (paragraph 0095) which represents alternate formulations, as stated in instant claims 10, 31, and 51. Levinson et al. disclose the solid-forms and pharmaceuticals which is any substance administered to humans such as prescription pharmaceuticals and over the counter pharmaceuticals (paragraphs 0040 and 0041) which represents administering of a pharmaceutical

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formulation, as stated in instant claims 20, 41, and 60. Levinson et al. disclose variations in the solid forms manufacturing (packaging) (paragraph 0008), structural property such as size (paragraph 0069), as well as formulas and concentrations (dosages) (paragraph 0095), as stated in instant claims 22-23, 43-44, and 62-63. Levinson et al. disclose selecting thousands of experimental formulations with three excipients (Merriam-Webster online dictionary defines as an inert substance used as a drug vehicle) and one or more active agents with experimental iterations being performed (paragraphs 0101, 0102, 0105, 0107, and 0108), which represents at least three batches of pharmaceutical compositions as stated in instant claims 66-69, 70, and 72-77. Thus, Levinson et al. anticipate claims 1-7, 10-11, 13-16, 20, 22-29, 31-32, 34-37, 41, 43-47, 49-52, 54-57, 60, 62-66, 68-70, and 72-81.

Applicant states incorporating the limitation of now cancelled claim 8 into amended claim 1 renders the 35 USC 102 rejection moot. This statement is found unpersuasive as a combination of limitations from cancelled claims 8 and 67 were amended into claim 1 whose limitations have been found in the prior art due to a reconsideration of the art.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG



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30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 24, 2005

 3/29/05  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER